

## REMARKS

The Applicant appreciates the courteous and complete examination of the application by the Examiner. In view of the foregoing amendments and the following remarks, a reconsideration of the instant application is respectfully requested.

In order to expedite the prosecution of this application, claims 1, 5 and 6 have been amended. Claims 2-4 have been cancelled without prejudice or disclaimer of the subject matter thereof. Claims 7-15 have been added to more completely cover certain aspects of the Applicant's invention. Claims 1 and 5-15 are now in this application.

The Examiner objects to claims 5 and 6 under 37 CFR 1.78(c) as being in improper form. Claims 5 and 6 have been amended to remove all multiple dependent claim objections.

The Examiner rejects claims 1, 3/1 and 4/3/1 under 35 U.S.C. 103(a) as being unpatentable over Vyakarnam et al. (6365149) in view of any of Bay et. (4650488), Schmitt (3620218) and Bowen (2127903).

The Applicant appreciates that the Examiner has located patents toward biodegradable prosthetic devices having relevant materials and configurations. In regards to the prior art references relied upon by the Examiner, claim 1 has been amended to incorporate all the limitations of cancelled claims 2 and 4. None of prior art references disclose or teach "wherein said tubular body, in an intermediate portion thereof comprised between said ends, has a greater biodegradability with respect to the biodegradability of said flange." This specific structural limitation is important since the tubular body will degrade faster than the flange, allowing for the flange to fall into the outer ear away from the insertion point. Additionally, as stated in paragraph [0014] of the present application, the benefit of this specific structural limitation is for "avoiding different mechanical stress on the tissues, as well as the risk of invagination and consequent cholesteatoma." The Applicant acknowledges that it is known to have varying rates of degradation of an implant, but the Hubbell et al. or the Tormala et al. reference do not show a motivation to combine a flange having a different biodegradability with a tubular device having a varying degree of biodegradability.

Additionally, the Examiner rejects to claims 2, 2/3 and 4/3/2 under 35 U.S.C. 103(a) as being unpatentable over Vyakarnam et al. as modified by the secondary

references as applied to claim 1 above, and further in view of either of Hubbell et al. (6060582) or Tormala et al. (6228111). Claims 2, 3 and 4 have been cancelled.

Moreover, the law is clear that a motivation must be provided by the prior art to make the allegedly obvious combinations of parts relied upon in making an obviousness rejection.

Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. See, e.g., *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 140, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998). And, absent such a showing of motivation in the prior art to make the allegedly obvious combination, it can only be assumed that the applicant's disclosure has provided the motivation for making the combination of elements from the prior art, and not the prior art itself.

Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability -- the essence of hindsight. See e.g., *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985).

It is therefore submitted that the combination of individual parts taught by the various prior art references relied upon in the Office Action would not motivate one skilled in the art to arrive at the applicant's claimed invention.

Claims 7-10 further adds limitations from the specification to cover certain aspects of the invention. None of the prior art references relied upon by the Examiner disclose, teach, or show motivation of a biodegradable flange located at the end of the tubular body having the greatest rate of biodegradability, as described in claim 7. Additionally, where the biodegradable flange has a pointed appendage adapted to perforate the tympanic membrane when inserted, as described in claim 8. The Applicant acknowledges that the Bay et al. reference does disclose a tab 18 formed on the lateral side of a flange 14, but this tab is only used "so that the tube I can easily be gripped during insertion", see column 3 lines 25-26. There is no teaching or motivation for having a pointed appendage specifically designed for perforating the tympanic membrane, as described in claim 8 of the present invention. The tab 18 is not pointed

and it is designed to be gripped by the user. It can be appreciated that the pointed appendage and its corresponding function is substantially different than the tab 18 in the Bay et al. reference. Claims 7-10 are felt to patentably distinguish over the prior art references because of their above-mentioned dependency from amended claim 1.

Claims 11-15 further adds limitations from the specification to cover certain aspects of the invention. Claims 11-15 are believed to patentably distinguish over the prior art references because of the above-mentioned explanations.

The Applicant requests that the Examiner reconsiders his rejections of the invention in view of the well established principle that small differences in a crowded art can constitute patentable improvement. See *In re Baum*, 51 USPQ 470 (CCPA 1941) and *In re Lange*, 126 USPQ 365 (CCPA 1960). In considering this principle, the Applicant would also request that the Examiner take note to the court decision which notes that "apparent simplicity has been held to furnish strong argument for patentability where, as here, a need has existed for a structure of the nature disclosed and claimed. The fact that a solution to a problem is simple, or appears to be simple when viewed in retrospect, does not mean that the solution was obvious when it was conceived." See *Ellipse corp. v. Ford Motor Co.*, 171 USPQ 513.

With the above amendments being fully responsive to all outstanding rejections and formal requirements, it is respectfully submitted that the claims are now in condition for allowance, and a notice to that effect is earnestly solicited. Should the Examiner feel that there are further issues which might be resolved by means of telephone interview, the Examiner is cordially invited to telephone the undersigned at (403) 444-5695, or email at davidguerra@verizon.net.

No additional fee is due.

Respectfully Submitted,

A handwritten signature in dark ink, reading "David A. Guerra". The signature is written in a cursive, flowing style with a large initial "D".

David A. Guerra, Reg. 46,443

**CERTIFICATE OF TRANSMISSION/MAILING**

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

On (Date) August 3, 2006 by David A. Guerra 